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| APPLICATION NO.               | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/561,191                    | 12/16/2005  | Masayuki Tsuchiya    | I254-0300PUS1       | 3952             |
| 2292                          | 7590        | 10/10/2007           | EXAMINER            |                  |
| BIRCH STEWART KOLASCH & BIRCH |             |                      | ROOKE, AGNES BEATA  |                  |
| PO BOX 747                    |             |                      | ART UNIT            | PAPER NUMBER     |
| FALLS CHURCH, VA 22040-0747   |             |                      | 1656                |                  |
| NOTIFICATION DATE             |             | DELIVERY MODE        |                     |                  |
| 10/10/2007                    |             | ELECTRONIC           |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[mailroom@bskb.com](mailto:mailroom@bskb.com)

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 10/561,191                 | TSUCHIYA ET AL.  |
|                              | Examiner<br>Agnes B. Rooke | Art Unit<br>1656 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 20 July 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-49 is/are pending in the application.  
 4a) Of the above claim(s) 1-18 and 24-49 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 19-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 16 December 2005 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date. \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

In the response to the restriction requirement on 7/20/2007, Applicants elected with traverse claims directed Group XII, claims 19-23 for prosecution.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP paragraph 821.01.

The Applicants traversed the restriction requirement on the grounds that Groups XIV and XV should be rejoined. Examiner disagrees because those two inventions are directed to a distinct subject matter, since Group XIV is directed to a method wherein the fucose already exists in the Golgi, and in Group XV, the incorporation of fucose into the Golgi is measured. Therefore the inventions are distinct. Next, Applicants argue that they are entitled to rejoinder when the product is allowable. Examiner agrees and the rejoinder practice will be appropriately applied when the product claims are found allowable. In addition, Applicants argue that all claims have in common the same single general inventive concept or special technical feature. However, Applicants do not provide any examples in their arguments what is the special feature and why is it special? Examiner responds that distinct groups were designated based on distinct product and distinct methods thus lacking a single general inventive concept or special technical feature as evidenced by the claimed distinct inventions, because a nucleotide of Group II is very different from an antibody of Group III, for example. Finally, Applicants insists that there is no undue burden to search the inventions and that examiner did not list classes and subclasses in the restriction. Examiner responds that there are distinct inventions claimed as evidenced by the restriction requirement and

that according to the PCT Rule 13.1 practice, examiner is not required to provide classes and subclasses in the restriction requirement. Therefore, the restriction is proper and thus final.

***Priority***

This application is a 371 of PCT/JP04/08956 filed on 06/18/2004, which claims foreign priority to JAPAN 2003-174010 filed on 06/18/2003, 2003-174006 filed on 6/18/2003, 2003-282081 filed on 07/29/2003, and 2003-282102 filed on 07/29/2003.

***Status of claims***

Claims 1-49 are pending. Claims 19-23 are currently under examination. Claims 1-18 and 24-29 are withdrawn.

***Information Disclosure Statement***

IDS submitted on 12/16/2005, 05/03/2006, 12/04/2006, 02/22/2007 have been reviewed and signed by the examiner.

***Drawings***

Drawings, filed on 12/16/2005, have been approved by the Draftsmen and are entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 19-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to a non-statutory subject matter. In the instant claims 19-23, Applicants refer to a product that occurs in its natural state, i.e. a *cell*, which is not isolated. Therefore, the product claimed must be isolated to be patentable.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 19-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants in claims 19-23 refer to a gene that is "disrupted," however the term is indefinite since it is not certain whether "disrupted" means that a gene is not expressed, or whether a cell express a mutant or whether it expresses different species, for example. Thus, further clarification of the term "disrupted" in the claims as presented is required.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Luhn et al., The gene defective in leukocyte adhesion deficiency II encodes a putative GDP-fucose transporter, Nature Genet., 28, pages 69-72 (2001).

Luhn et al. teach that to identify the gene mutated in leukocyte adhesion deficiency II ("LAD II"), they cloned 12 cDNAs from C. elegans, encoding multi-spanning transmembrane proteins with homology to known nucleotide sugar transporters, and transfected them into fibroblasts from LAD II patient, where the putative GDP-fucose transporter was identified. (See Abstract on page 69) (claims 19 and 20). Also, for complementation, they co-transfected LAD II fibroblast from a patient with a vector DNA containing cDNA containing a gene of interest. (See page 72, left column, bottom paragraph). (claim 23).

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luhn et al., The gene defective in leukocyte adhesion deficiency II encodes a putative GDP-fucose transporter, Nature Genet., 28, pages 69-72 (2001) in view of Kao et al.,

Genetics of somatic mammalian cells, VII. Induction and isolation of nutritional mutants in Chinese hamster cells, Proc. Natl. Acad. Sci. USA, 60, pages 1275-1281 (1968).

The teachings of Luhn et al. are disclosed above when Luhn et al. do not teach Chinese hamster cells.

Kao et al. teach Chinese hamster ovary cell that was used for cloning purposes. (See pages 1275-76 for section of Materials and Methods).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to design a cell where the fucose transporter gene is disrupted and a vector is used to disrupt a fucose gene as taught by Luhn et al. and to further use a Chinese hamster cell to apply gene targeting vector as taught by Kao et al. It would be obvious to replace one cell type with another type since different cell lines can be used for genetic manipulation purposes, and animal cells, such as Chinese hamster cell or CHO cell are commonly known and used in the art.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300. Information regarding the status of an application may be obtained from the

Art Unit: 1656

Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR

*Karen Cochrane Carlson P.D.*

KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER